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Pesticide Fact Sheet Number 2.1: Cryolite

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

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EPA

Pesticide Fact Sheet

Name of Chemical: CRYOLITE
Reason for Issuance: REGISTRATION STANDARD
Date Issued: APRIL 1988
Fact Sheet Number: 2.1

1. DESCRIPTION OF CHEMICAL

Generic name: (Chemical) Sodium aluminofluoride or sodium fluoaluminate

Common name: Cryolite

Trade Names: Kryocide and Prokil

Other Chemical Nomenclature: trisodium hexafluoroaluminate, sodium hexafluoroaluminate, and sodium aluminum fluoride

EPA Pesticide Chemical (Shaughnessy) Number: 075101

Chemical Abstracts Service (CAS) number: 15096-52-3 (Merck Index)

Year of initial registration: 1959

Pesticide type: Insecticide

Chemical family: Inorganic fluorine compound

U.S. Registrants: Agchem Division of Pennwalt Corp., Amvac Chemical, Gowan Co. and Moyer Products, Inc.

2. USE PATTERNS AND FORMULATIONS

Application sites: Terrestrial food crop use on apples, beans, beets, broccoli, Brussels sprouts, cabbage, cantaloupes, carrots, cauliflower, collards, cranberries, cucumbers, eggplant, grapefruit,

grapes, kale, kohlrabi, kumquats, lemons, lettuce, limes, melons, mustard greens, oranges, pears, peppers, pumpkins, radishes, squash, strawberries, tangerines, tomatoes, turnips, and watermelons.

Terrestrial non-food crop use on ornamental trees and shrubs (including nursery stock).

Formulations: Wettable powders and dusts

Methods of application: Aerial or ground, foliar application as a spray or dust

Application rates: rates from 5 to 78.98 lb ai/A

3. SCIENCE FINDINGS

Summary Science Statement

Technical cryolite is mildly toxic on an acute oral, dermal and inhalation basis (Toxicity Category IV, III and III, respectively.) Cryolite does not demonstrate a teratogenic, fetotoxic, or mutagenic potential. The Agency has concerns about the potential adverse health effects of fluoride to bones, as well as the potential adverse cosmetic effects of fluoride to the teeth of children, resulting from the pesticidal application of cryolite. These concerns are based upon findings of crippling skeletal fluorosis in adults who were chronically exposed to relatively high levels of fluoride and extensive epidemiological studies with large populations of children carried out over the last 40 years[1]. The Agency cannot set a reference dose (RfD) for cryolite until additional data are submitted, specifically, a rat metabolism (pharmacodynamic) study to quantitate the bioavailability of fluoride from cryolite. Information derived from this study should allow the Agency to establish a RfD for cryolite. None of the tolerances for cryolite are adequately supported, and residue data are required to support all crop uses.

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[1] In 1986, the Agency's Reference Dose Work Group established a reference dose (RfD) of 0.12 mg/kg/day for fluoride (designed to prevent the development of crippling skeletal fluorosis), and also established an additional value of 0.06 mg/kg/day for fluoride. This additional value is designed to prevent the development of objectionable dental fluorosis in children.

There are no groundwater concerns identified for this chemical. A confined rotational crop study is required because preliminary residue chemistry data show tolerance-exceeding levels of fluorine and/or cryolite in primary crops following direct treatment with cryolite, allowing for a possibility that residues will also occur in rotational crops.

Cryolite is not expected to pose an acute hazard to fish and wildlife based on acceptable acute and subacute studies which show that technical cryolite is practically nontoxic to birds and bees, and only slightly toxic to fish and aquatic invertebrates. However, aerial application of cryolite at ≥30 lb ai/A may pose a chronic hazard for aquatic invertebrates. Therefore, an aquatic invertebrate life cycle study is required to support these uses.

Chemical/Physical Characteristics of the Technical Material

Chemical/Physical Characteristics: Cryolite is a naturally occurring mineral (large deposits occurring in Greenland and the Urals), or it may be synthetically produced by the reaction of aluminum oxide, sodium chloride, and hydrogen fluoride.

Color: white (natural); white to yellow-brownish white (synthetic)
Physical state: powder (natural); glassy powder at 20° C (synthetic)
Odor: none (natural and synthetic)
Melting Point: 1000° C (Merck Index)

Toxicology Characteristics

Acute Oral: Toxicity Category IV (LD_{50} > 5 g/kg in the rat)

Acute dermal: Toxicity Category III (LD_{50} > 2.1 g/kg in the rabbit)

Acute inhalation: Toxicity Category III (LD_{50} >2.06 mg/L and < 5.03 mg/L in the rat

Primary dermal irritation: Toxicity Category IV (rabbit: P.I. score = 0.0; not an irritant)

Primary eye irritation: Toxicity Category III (in rabbit: moderate conjunctival irritation that disappeared within 7 days)

Skin sensitization: Non-sensitizing

Delayed Neurotoxicity: Cryolite is not an organophosphate and therefore a study is not required.

Subchronic dermal toxicity: Data gap. A 21-day dermal toxicity study is required.

Subchronic feeding studies: Studies reviewed were classified supplementary because a NOEL for fluoride accumulation in the bone could not be established.

Mutagenicity: Cryolite was negative in the Ames assay for mutagenic activity; in the DNA repair test using Escherichia coli for genotoxic effects; and in a rat in vivo cytogenetics assay for structural chromosome aberrations.

Teratogenicity: No teratogenic or fetotoxic effects noted at the highest dose tested in a rat study (NOEL > 3000 mg/kg/day).

Metabolism: Data gap. A rat metabolism (pharmacodynamic) study is required.

Chronic Toxicity: Data gap. Chronic toxicity studies (rat and dog) are required.

Oncogenicity: Data gap. Oncogenicity studies (rat and mouse) are required.

Reproduction: Data gap. A 2-generation rat reproduction study is required.

Magnitude of the Residue in Plants: Data gaps. Field crop trials and processing studies are required.

Environmental Characteristics

Cryolite is only slightly mobile in soil. It does not hydrolyze, but rather dissociates, yielding free fluorine at pH 5, 7, and 9. Cryolite is not expected to contaminate groundwater, since it is only slightly mobile in soil. Submitted residue chemistry data show that tolerance-exceeding levels of fluoride and/or cryolite will occur in food crops following direct treatment with cryolite and hence the possibility of residues occurring in rotational crops. A confined rotational crop study is required. The requirement for a field rotational crop study is reserved, pending receipt and evaluation of the confined study.

Ecological Characteristics

Based on acceptable acute data, technical cryolite has been determined to be practically non-toxic to birds and bees, and slightly toxic to freshwater fish and aquatic invertebrates.

- Acute LD_{50} (bobwhite): >2,150 mg/kg (practically nontoxic)
- Dietary LC_{50} (mallard duck and bobwhite): >10,000 ppm (practically nontoxic)
- Freshwater invertebrate toxicity (96-hr LC_{50}) for Daphnia pulex: 10 ppm; for Daphnia magna: >100 ppm (slightly toxic)
- Fish acute toxicity (96-hr LC_{50}) for rainbow trout: 47 ppm (slightly toxic)
- Fish acute toxicity (96-hr LC_{50}) for bluegill sunfish: >400 ppm (practically nontoxic)
- Acute toxicity to honeybees: 1.45% mortality at 217 mg per bee

The aquatic estimated environmental concentration (EEC) resulting from indirect application (i.e., runoff and spray drift) of cryolite exceeds the criteria for requiring the aquatic invertebrate life cycle test (i.e., >1% of the acute toxicity value for the most sensitive species) when cryolite is applied aerially at ≥30 lb ai/acre. Therefore, the test is required for all products allowing for application under these conditions.

Tolerance Assessment

Tolerances for residues of cryolite in or on food commodities are published in 40 CFR 180.145. These tolerances are expressed in terms of combined fluorine for residues of the insecticidal fluorine compounds cryolite and synthetic cryolite. They are set at 7 ppm for all listed commodities.

Data are not available regarding the metabolism of cryolite in plants. Although the Agency recognizes that traditional plant metabolism studies using radiolabeled materials may not be useful or practical for cryolite (an inorganic compound), studies showing the form of fluoride (cryolite per se vs. free fluoride ion) in or on raw agricultural plant commodities could provide useful information regarding the nature of the residue as consumed by humans and livestock. Development of an analytical method for distinguishing between cryolite per se and free fluoride ion is required. This method must be used in selected residue field trials so that a residue profile (cryolite per se vs. total fluoride) can be

developed. The metabolism of cryolite in animals is not adequately understood. No data have been submitted pertaining to the metabolism of cryolite in ruminants or poultry. This requirement is deferred until the required rat metabolism (pharmacodynamic) study has been submitted and reviewed.

An adequate method is available for enforcement of tolerances and data collection for residues of cryolite in or on plant commodities. The limit of detection for fluorine is 0.1 ppm. Cryolite is not expected to degrade during storage because it is a naturally occurring mineral.

Field trial studies are required for all crops for which there are cryolite tolerances. Processing studies are also required. Tolerances (or feeding/grazing restrictions) must be proposed and appropriate supporting residue data submitted for the raw agricultural commodities and feed items - bean vines and hay. Separate tolerances must be proposed for succulent and dry beans. Food/feed additive tolerances must be proposed for the combined fluorine residues of cryolite and synthetic cryolite in grape pomace, raisins, and raisin waste, and in paste, puree and catsup of tomatoes, since residues have been observed to concentrate in these commodities.

4. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

- Cryolite does not meet the criteria for restricted use classification.
- Cryolite is not a candidate for Special Review.
- There are no groundwater concerns identified for this pesticide.
- The Agency will not approve any significant new food uses until the Agency has received residue chemistry data and toxicology data ((rat metabolism (pharmacodynamic) study) sufficient to allow the Agency to perform a tolerance reassessment.

SUMMARY OF REQUIRED LABEL MODIFICATION

- An updated Environmental Hazard Statement is required.

SUMMARY OF OUTSTANDING DATA REQUIREMENTS

	Due Date[2]
Toxicology	

[2] Due date is measured from the date of receipt of the Standard by the registrant unless otherwise specified.

21-day dermal toxicity	9 months
Metabolism (pharmacodynamic)	24 "

	Due Date
Chronic Toxicity (rodent and non-rodent)	50 Months
Oncogenicity (rat and mouse)	50 "
Reproduction (rat)	39 "
Environmental Fate/Exposure	
Confined rotational crop study	39 "
Fish and Wildlife	
Aquatic invertebrate life-cycle study	15 "
Residue Chemistry	
Residue data - raw agricultural commodities	18 "
Processing studies	24 "
Plant metabolism	18 "
Product Chemistry	
Majority of Data	9 -15 "

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